the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 15, 1994, which was 30 days after FDA receipt of the IND.'' The document should have stated: ''1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: January 15, 1989. The applicant claims January 14, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 15, 1989, which was 30 days after FDA receipt of the IND.'' This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

In FR Doc. 94–22760, appearing on page 47341 in the **Federal Register** of September 15, 1994, the following corrections are made:

On page 47341, in the second column, in the third paragraph, in the fourth and ninth lines, ''January 15, 1994'' is corrected to read ''January 15, 1989''.

Dated: December 21, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94–32242 Filed 12–30–94; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HSQ–224–N]

CLIA Program: Approval of the Joint Commission on Accreditation of Healthcare Organizations As An Accrediting Organization

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by JCAHO in lieu of receiving direct Federal oversight and continue to meet JCAHO requirements would meet the CLIA condition level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period January 3, 1995 through January 3, 1997.

FOR FURTHER INFORMATION CONTACT: Tracey Mummert, (410) 597–5906.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA replaced in its entirety section 353 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS and Federal regulation whether or not it participates in the Medicare or Medicaid program and whether or not it tests specimens in interstate commerce. New section 353 requires HHS to establish certification requirements for any laboratory that performs tests on human specimens and certify through issuance of a certificate that those laboratories meet the certificate requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs or both. Laboratories that are accredited by an accreditation organization approved under section 353 of the PHSA will automatically be eligible for Medicare and Medicaid participation as long as they meet applicable State licensure requirements.

On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002–7243) that implemented the amendments to section 353 of the PHSA. In a subsequent rule published January 19, 1993 (58 FR 5215), we added ''certificate for physician-performed microscopy procedures'' and amended some of the performance requirements previously published on February 28, 1992.

On July 31, 1992, we issued final rules (57 FR 33992), under authority found in section 353(e)(2) of the PHSA, that permit HCFA to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements established at 42 CFR part 493 of our regulations. Under § 493.501(d) of our regulations the approval period may not exceed six years.

In general, the accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS;
- Apply standards and criteria that are equal to or more stringent than those condition level requirements established by HHS when taken as a whole;
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HHS, within 30 days, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;
- Notify HHS at least 30 days prior to changing its standards; and
- If HHS withdraws its approval, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA requires HHS to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that HHS determines appropriate. Under section 353(o) of the PHSA, the Secretary may, by agreement, use the services or facilities of any other Federal, State or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

II. Notice of Approval of JCAHO as an Accrediting Organization

In this notice, we approve JCAHO as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty/subspecialty areas.

As a result of this determination, any laboratory that is accredited by JCAHO during the effective time period for an approved specialty/subspecialty meets the CLIA requirements for laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by HCFA, or by any other Federal or State or local public agency or nonprofit private organization which acts in conformance to an agreement with the Secretary.

III. Evaluation of the JCAHO Request for Approval as an Accreditation Organization under CLIA

JCAHO has formally applied to HCFA for approval as an accreditation organization under CLIA for all specialties and subspecialties. We have evaluated the JCAHO application for approval to serve as an accrediting organization under CLIA, to determine equivalency with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We also verified the organization's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of 42 CFR part 493 as explained below:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

JCAHO has submitted a list of the specialties and subspecialties that it would accredit; a comparison of individual accreditation and condition level requirements; a description of its inspection process, Proficiency Testing (PT) monitoring process, and its data management and analysis system; a listing of the size, composition, education and experience of its inspection teams; its investigative and complaint response procedures; its notification agreements with HCFA; its removal or withdrawal of laboratory accreditation procedures; its current list of accredited laboratories; and its announced or unannounced inspection process.

The JCAHO accreditation process is more stringent than Federal certification requirements in that JCAHO accredits a healthcare organization (for example, hospital) as a whole and not just the laboratory alone. As such, an organization that loses its JCAHO accreditation for reasons other than poor laboratory performance would also lose its ability to legally test human specimens under the laboratory's existing certificate of accreditation, if JCAHO accreditation is being used to meet the CLIA requirements. The laboratory would then need to reapply to HHS, within 45 days, for an appropriate CLIA certificate to continue to perform laboratory testing.

JCAHO has additional requirements pertaining to waived testing. These requirements address the intended use of the waived test (that is, screening, diagnosis, monitoring); identification of individuals responsible for test performance and for direction/supervision of testing activity; training and competence in test performance; written policies and procedures for specimen collection and preservation, instrument calibration and performance evaluation, quality control, test performance, and remedial action; defined quality control checks; and the maintenance of quality control and test records. Sites within the organization performing waived testing will be routinely surveyed. As set forth at 42 CFR 493.15, CLIA requires only that a laboratory follow manufacturer's instructions and does not require routine inspections of waived testing.

We have determined that JCAHO has complied with the general requirements under § 493.501, the applicable parts of § 493.506, and the CLIA requirements for approval as an accreditation organization under various subparts of part 493.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

JCAHO has revised its requirements to be equivalent to the CLIA requirements at §§ 493.801 through 493.865 on an overall basis.

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

JCAHO has revised its requirements to be equivalent to the CLIA requirements at §§ 493.1101 through 493.1111 on an overall basis.

Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both

The quality control (QC) requirements of the JCAHO have been evaluated against the requirements of the CLIA regulations. JCAHO has modified its survey process and made revisions to its standards encompassing general QC requirements as well as specialty and subspecialty QC in order to address some of the more specific QC requirements of CLIA. As such, we have determined that JCAHO's requirements, when taken as a whole, are equal to or more stringent than the CLIA requirements. The specific areas of QC that are more stringent are:

- Compliance with all Federal, State, and local laws including the applicable National Fire Protection Association safety code requirements regarding employee and patient health and safety;
- Requirements that laboratories must meet JCAHO's QC requirements for all waived testing that they perform;
- No phase-in of quality control requirements except that laboratories performing unmodified, moderate complexity tests may meet the calibration requirements of § 493.1202(c);
- A requirement that laboratories maintain histocompatibility records for 5 years;
- A requirement that for mycobacteriology, laboratories perform daily QC for fluorochrome acid-fast stains;
- A requirement that laboratories perform QC on permanent stains in parasitology with each use;
- A requirement that for mycology, laboratories perform QC using both positive and negative controls each day of use for acid-fast stains;
- For cytology, JCAHO requires the review of all normal or negative gynecological specimens, and encourages the review of all abnormal gynecologic specimens received in the laboratory within the past 5 years when a current determination of a high grade intraepithelial lesion or above exists.

Subpart M—Personnel for Moderate and High Complexity Testing

JCAHO has revised its requirements to equal the CLIA requirements at §§ 493.1403 through 493.1495 on an overall basis. JCAHO states, as general policy under its personnel standards, that the laboratory must meet CLIA requirements for personnel qualifications. The CLIA requirements for personnel responsibilities are encompassed in the revisions made to JCAHO standards.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

JCAHO has revised its requirements to be equivalent to the CLIA requirements at §§ 493.1701 through 493.1721 on an overall basis.

Subpart Q—Inspections

JCAHO has made revisions to its inspection process, which is announced, and will perform on-site

inspections of the laboratory on a biennial basis, to equate to the applicable CLIA requirements at §§ 493.1777. In citing deficiencies, JCAHO uses a system of weighting multiple standards that aggregate to a single grid element. This system has been somewhat modified for laboratories such that weight does not preclude laboratories from correcting any deficiencies that relate to CLIA requirements. Therefore, we have determined that JCAHO's requirements are equivalent to the requirements of this subpart.

Subpart R—Enforcement Procedures for Laboratories

JCAHO meets the requirements of subpart R to the extent it applies to accreditation organizations. JCAHO policy stipulates the action it takes when laboratories it accredits do not comply with its essential standards. When appropriate, JCAHO will deny, revoke or conditionally accredit a laboratory and report that action to HCFA within 30 days. JCAHO also provides an appeals process for laboratories that have had accreditation denied or revoked.

Some specific actions JCAHO takes in response to non-compliance or violation of essential standards include:

• When JCAHO determines that a serious risk of harm (immediate jeopardy) situation exists in a JCAHO-accredited laboratory, the laboratory must immediately correct the problem that poses the risk. Failure to do so will result in a recommendation to the JCAHO Accreditation Committee to revoke that facility's accreditation. In addition, JCAHO will notify HCFA within 10 days of this determination.

• When a JCAHO laboratory is unsuccessful in PT participation for a Federally required analyte, subspecialty, and/or specialty, the laboratory will be contacted by JCAHO and required to initiate corrective actions. Failure to submit an acceptable proficiency outlier action report (POA) may result in an unscheduled, onsite survey and limitation of the laboratory's scope of accreditation for the particular analyte, specialty, and/or subspecialty. To regain accreditation, the laboratory must provide JCAHO evidence that it has successfully participated in two consecutive PT events.

We have determined that JCAHO's laboratory enforcement and appeal policies are essentially equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

Federal validation inspections and continuing oversight of JCAHO accredited laboratories will be conducted based on the regulations at 42 CFR 493.507 and 493.509.

V. Removal of Approval as an Accrediting Organization

Our regulations at § 493.511 provide that the approval of an accreditation organization, such as that of JCAHO, may be removed by HCFA for cause, prior to the end of the effective date of approval. If it is determined that JCAHO has failed to adopt requirements that are equal to or more stringent than the CLIA requirements, or that systemic problems exist in its inspection process, a probationary period, not to exceed one year, may be given to allow JCAHO to adopt comparable requirements.

Should circumstances result in JCAHO having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: December 1, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 94–32203 Filed 12–30–94; 8:45 am]

BILLING CODE 4120–01–P

[BPO–129–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Third Quarter 1994

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations and other **Federal Register** notices, and statements of policy that were published during July, August, and September of 1994 that relate to the Medicare and Medicaid programs. Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

We are also providing the content of revisions to the Medicare Coverage Issues Manual published between July 1 and September 30, 1994. On August 21, 1989, we published the content of the Manual (54 FR 34555) and indicated that we will publish quarterly any updates. Adding to this listing the complete text of the changes to the Medicare Coverage Issues Manual allows us to fulfill this requirement in a manner that facilitates identification of coverage and other changes in our manuals.

FOR FURTHER INFORMATION CONTACT:

Margaret Cotton, (410) 966–5255 (For Medicare instruction information)

Walter Rutemueller, (410) 966–5395 (For Medicare coverage information)

Pat Prete, (410) 966–3246 (For Medicaid instruction information)

Michael Robinson, (410) 966–5633 (For all other information)

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 36 million Medicare beneficiaries and 33 million Medicaid recipients. Administration of these programs involves (1) Providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public; and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers who process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under authority granted the Secretary under sections 1102, l871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the **Federal Register** at least every 3 months a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month timeframe. Since the publication of our